

ADMISSIBILITY OF PET SCAN EVIDENCE IN MILD TRAUMATIC BRAIN INJURY CASES

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In cases of mild traumatic brain injury (MTBI) the results of neurodiagnostic testing are usually negative. This is because the standard tests such as computerized axial tomography (CT) and magnetic resonance imaging (MRI) depict brain structure and lack the resolution to visualize the microscopic damage which occurs in MTBI cases. Positron emission tomography (PET) is a computerized scanning technique that produces a picture showing the distribution of radioactivity in the brain after the injection of a radioactive isotope. Whereas CT and MRI show a static picture of brain structure, PET reflects brain function by showing metabolic activity in different areas of the brain. It provides an illustration of brain dysfunction by monitoring alterations in the amount of glucose that specific areas of the brain consume.

In *Wolfen v. Shaw* (1998), 43 B.C.L.R. (3d) 190 (S.C), I argued unsuccessfully that the results of a PET scan should be admitted into evidence in a mild MTBI case to establish the existence of abnormal metabolic activity in the brain of the Plaintiff. Dillon, J. ruled that the PET scan was not admissible as the evidence did not meet the test of "novel scientific evidence" which requires that the Plaintiff establish the reliability of PET in cases of MTBI.

I argued that the PET scan was not a novel scientific procedure. The Society of Nuclear Medicine Brain Imaging Council, in a consensus report titled "Ethical Clinical Practice of Functional Brain Imaging" published in the *Journal of Nuclear Medicine* 1994 Vol. 37(7) 1256 commented:

The use of SPECT and PET in the management of patients with stroke, epilepsy, brain tumors and dementia, and in some cases, movement disorders and moderate-to-severe head trauma is now well recognized.

While SPECT and PET can clearly be used to delineate functional abnormalities of the brain regardless of the cause it is only after careful study, as has occurred to date with cerebrovascular disease, dementia and epilepsy, that any cause-and-effect or prognostic associations can be made.

If the use of the PET to delineate functional abnormalities of the brain regardless of the cause is well recognized in cases of moderate to severe traumatic brain injury (TBI), why should the PET be excluded from consideration in cases of MTBI?

In the *Wolfen* case, the PET scan was performed in 1996 by Dr. Joseph Wu, a psychiatrist and Acting Director of the Brain Imaging Center at the University of California, Irvine. Dr. Wu testified during a voir dire to determine the admissibility of the PET scan. In his evidence he

referred to the relevant scientific literature and in particular the work of Dr. Abass Alavi, an internationally recognized expert and pioneer in the field of PET scanning.

Dr. Alavi is a professor of radiology, neurology and psychiatry, and Chief of the Division of Nuclear Medicine at the University of Pennsylvania School of Medicine. He is also Associate Editor of the *Journal of Nuclear Medicine* and was one of the authors of the consensus report of the Society of Nuclear Medicine Brain Imaging Council published in the *Journal of Nuclear Medicine*. (This is the same article relied upon by Dillon, J. when she found that the procedure recommended by the Council for PET scan interpretation and reporting was not followed by Dr. Wu. In fact the practice of nuclear radiologists is to provide a report similar to a CT scan or MRI report although this evidence was not before Dillon, J.)

Dr. Alavi is co-author of an article "Neuroimaging in Patients with Traumatic Brain Injury", published in the December 1996 edition of the *Journal of Head Trauma Rehabilitation* at pages 65-79. In the article Dr. Alavi and his co-author, Dr. Newberg, provide a comprehensive review of the literature dealing with the role of PET scans in traumatic brain injury and conclude their article with the following comments:

Neuroimaging is a crucial technique in the evaluation and management of head trauma. CT is considered the imaging modality of choice in the management of acute brain injury. CT provides a rapid assessment of major brain injuries, is readily available in most medical institutions, and is of relatively little cost. It provides information about intracranial bleeding with the possibility of subsequent mass effect that may require immediate surgical intervention. CT is also the most useful technique for detecting bone injuries such as fractures. However, CT does not have the sensitivity for detecting parenchymal lesions when compared with MRI. Although MRI is more expensive, it is becoming widely available and is superior to CT for detecting intracranial lesions and hemorrhage. Despite the extensive use and significance of anatomic imaging techniques in the evaluation of patients with head trauma, it has yet to be determined whether the lesions seen on CT or MRI correlate well with cognitive dysfunction and overall outcome. In fact, studies to date show that this poor correlation may be one of the major limitations of MRI and CT.

The functional imaging techniques of PET and SPECT are complementary to anatomic imaging and provide additional pathophysiologic and clinical information. PET and SPECT can reveal areas of hypometabolism or hypoperfusion that are not detectable by MRI or CT. PET and SPECT can also detect more lesions than CT. However, it has not yet been shown whether PET and SPECT can detect more lesions than MRI. MRI is especially sensitive for detecting very small lesions because of its high contrast resolution; however, the clinical relevance of these lesions remains uncertain. PET and SPECT do not have the resolution of MRI, but their ability to measure cerebral function may be more important for evaluating brain injury. Furthermore, studies to date have shown that PET and SPECT correlate

better with outcome and cognitive dysfunction than do either MRI or CT. This may be of particular value in the long-term management of head trauma patients, since determination of brain function may help in the evaluation of outcome after rehabilitation. Thus, functional imaging can identify areas of dysfunction that may not be detected by a particular neuropsychological battery and can define which abnormal sites improve over time. Currently, PET is not widely available for use in most medical centers, and therefore its use for acute head trauma patients is quite limited at this time. SPECT is more available and less costly than PET and therefore is more practical than PET for the routine evaluation of brain injury. Despite continual improvement in the resolution of SPECT with the use of new software and improved cameras (such as those with triple or quadruple heads), SPECT is still limited by its poorer resolution and difficulty in obtaining quantitative data compared to PET. Furthermore, SPECT allows for the measurement of CBF and does not provide metabolic information. Since there is an uncoupling of blood flow and metabolism in the early stages of brain injury, measurement of CBF without assessment of cerebral metabolism is of limited value in both the investigation and the management of patients with head trauma.

CT will remain the primary neuroimaging technique in the initial evaluation of the acute head trauma patient. However, MRI, PET, and SPECT each offer important useful information that may complement one another in determining the pathophysiology of , extent of injury, and outcome in patients with brain injury. Furthermore, as the need for the rehabilitation of patients with brain injury is emphasized, the role of functional imaging may become significantly enhanced in helping predict recovery, as well as in following patients as they clinically improve.

In *Wolfen*, the defence relied upon a report by another leading expert in PET scans, Dr. Helen S. Mayberg. Dr. Mayberg did not testify, but in the cross-examination of Dr. Peter Conti, the defence nuclear radiologist from California, I referred to an article by Dr. Mayberg "Frontal Lobe Dysfunction in Secondary Depression" published in the *Journal of Neuropsychiatry and Clinical Neurosciences*, 1994 Vol. 6 at 429. She refers to the wide use of PET to measure abnormal brain functioning in clinical studies:

An important application of PET and SPECT scanning since their introduction has been to study patterns of abnormal function in patients with well-characterized and, generally, pathologically confirmed diseases. The results have had a tremendous impact on both diagnosis and management of patients with epilepsy, brain tumors, and dementia, as well as a growing role in the evaluation of stroke, movement disorders, and *head trauma*. Scan abnormalities have also been identified in groups of patients with certain well-defined psychiatric diagnoses. These include depression; schizophrenia; panic, attention-deficit, anxiety, and obsessive-compulsive disorders; alcoholism; and substance abuse, among others. Although the sensitivity and specificity of these patterns has not been fully

established, these types of studies provide unrivaled tools for identifying previously unrecognized brain abnormalities and potential disease mechanisms in a variety of neuropsychiatric illnesses, including depression. [Emphasis added]

Dr. Mayberg authored another article, "Clinical Correlates of PET and SPECT Identified Defects in Dementia" published in the *Journal of Clinical Psychiatry*, 1994, Vol. 55(11) (supp) 1 in which she stated:

Positron emission tomography (PET) and single photon emission computed tomography (SPECT) provide another view of regional brain function. Under resting conditions, abnormal patterns of blood flow or metabolism can be measured in patients with particular clinical deficits or known diseases, analogous to anatomical lesion-behavior correlations. In addition, changes in regional blood flow or metabolism accompanying neural activity can be detected when healthy subjects or patients perform specific cognitive tasks. With these approaches, as with other types of physiologic mapping, the regional components of brain circuits regulating specific behaviors can be defined and abnormalities evaluated in specific patient populations.

Pattern identification in patients with well-characterized and often pathologically confirmed diseases has led to the routine use of PET and SPECT scans in the diagnostic workup and treatment of patients with epilepsy and brain tumors and a growing role in the evaluation of strokes, movement disorders, *head trauma*, and dementia. *Functional imaging studies in many of these clinical situations provide unique information, significantly augmenting that obtained with anatomical methods.* [Emphasis added]

Dr. Conti did not dispute that the pathophysiological mechanism responsible for traumatic brain injury is the same for mild, moderate and severe injuries. His literature review revealed 32 cases investigating the use of PET in MTBI cases and 75 in moderate to severe TBI cases. His concern was that there were insufficient studies to establish PET as a reliable neurodiagnostic test in cases of MTBI.

In cross-examination Dr. Conti agreed with the following excerpt from the article "Promising Techniques in the Assessment of Mild Head Injury" published in *Seminars in Neurology* in March 1994:

Closed head injury may result in varying degrees of brain injury, from slight to severe and irreversible. Severe or even moderate head injuries often result in obvious structural damage, which is usually easily detected by imaging or neurophysiologic assessment. Mild head injuries (MHI; defined by Rimel et al as a period of unconsciousness less than 20 minutes, a Glasgow Coma Scale of 13 or greater, a negative neurologic examination, and a duration of posttraumatic

amnesia less than 48 hours) are typically more subtle. In spite of persisting symptomatology, there is typically no anatomic evidence of injury as traditionally assessed. (See Young and Silberstein in this issue of *Seminars*).

A variety of distressing symptoms often follow MHI or neck injury. The most common are headache, dizziness, impaired concentration, memory difficulties, fatigue, irritability, depression, and anxiety. Paradoxically, individuals sustaining MHI often have more intense posttraumatic symptoms than those who sustain more severe head injuries. The persistence of these symptoms often results in feelings of distrust from the public, the legal profession, insurance companies, and even other physicians. Even in the face of legitimate posttraumatic symptoms, patients may still be labeled as "accident neurosis," "personality disorder," or "malingering in order to receive compensation."

New technologic advances in experimental head injury and neuroimaging techniques have revealed that even MHIs result in subtle changes in the structure and physiology of the brain: Such cerebral alterations may explain the persistence of memory difficulties, depression, distractibility, dizziness and headache. *Traditional studies, however, including radiographs, electroencephalography (EEG), computerized tomography (CT), and magnetic resonance imaging (MRI) are often normal in MHI. Transcranial Doppler (TCD), positron emission tomography (PET), single photon emission computerized tomography (SPECT), and quantitative analysis of EEG and evoked potentials (brain mapping) have only recently become available for clinical use.* These new and promising techniques will be reviewed in detail in this article.

PET may be most useful as a diagnostic tool. It has been used to study a wide range of neurologic and psychologic disorders. Alzheimer's disease, multi-infarct dementia, and epilepsy have characteristic metabolic patterns. PET can often identify these diseases in their early stages, where MRI and CT cannot. Depression may also be distinguished metabolically from dementia or Alzheimer's disease. PET has been used to correlate cognitive abnormalities with areas of the brain. Cerebral glucose metabolism is decreased in frontal areas in schizophrenic patients compared with controls.

In head trauma patients, PET has revealed widespread abnormalities in cerebral glucose metabolism. Alavi and colleagues reported that PET revealed disturbances of metabolism beyond the structural abnormalities illustrated by MRI and CT.

[Emphasis added]

The essence of the defence argument in *Wolfen* was that the PET scan, while an appropriate procedure for cases of moderate to severe brain injury, was not ready to be used for clinical purposes in cases of MTBI due to insufficient studies confirming its reliability and accuracy in

detecting functional changes due to MTBI. I argued that this was an artificial distinction given the defence expert's evidence that the pathophysiological mechanism was the same for a mild, moderate, or severe TBI. If, as stated by The Society of Nuclear Medicine Brain Imaging Council that "· PET can clearly be used to delineate functional abnormalities of the brain regardless of the cause·", why should the PET be excluded from consideration in cases of MTBI?

A PET scan could not be used in isolation to establish that the metabolic abnormality was caused by the trauma of a motor vehicle accident any more than an X-ray could be used to establish that a bone fracture was caused by a particular traumatic event or that a high temperature measured by a thermometer was caused by the patient's fever. It simply establishes the existence of an abnormality. The casual relationship to a particular event is determined by the trier of fact after all of the evidence is considered. Thus, I argued in *Wolfenbarger* that the issue should be the interpretation and weight to be given to the PET scan evidence, not its admissibility.

This was the analytical approach taken by the Superior Court of the State of California in a more recent case, *Cassady v. Los Angeles County*, March 16, 1998, Case No. VC 022335. The Court referred to the following legal ground rules for the admissibility of new scientific techniques:

The seminal case in California establishing the legal ground rules for the admissibility of new scientific techniques is *People v. Kelly* (1976) 17 Cal. 3d 24. Kelly enunciated a 3-prong test. New scientific techniques may be received in evidence if the proffering party has established:

1. the reliability of the method in general; the evidence of reliability is furnished by a properly qualified expert; and
2. proper scientific procedures have been employed to produce the results being proffered.

Reliability is the key prong of the test and requires "...a preliminary showing of general acceptance of the new technology in the relevant scientific community." (Ibid. at pp.30-31)

"General acceptance" has still not been defined with precision: we know that unanimity is not required (*People v. Guerra*) (1984) 37 Cal. App. 3d 385, 418) and that it takes more than a single opinion (Kelly, supra, 17 Cal. 3d at p.37.).

Within that range, *Guerra* states that acceptance means "clear majority" (Guerra, supra. 37 Cal.App.3d at p.418) and the court in *People v Brown* (1985) 40 Cal. 3d 512 writes that acceptance means "the consensus" (Ibid. at p.532).

In deciding whether this elusive point of general acceptance has been reached by the evidence, the court may consider; expert testimony in the present case, scientific literature and publications ("...scientists (may) speak to the courts through their published writings...") *People v. Shirley* (1982) 31 Cal. 3d 18 56; decisions from

other jurisdictions; other proceedings in the same court by judicial notice. (Ibid. at p.54).

It is well established that the court is not required to become an instant expert, but only to conduct a "fair overview" sufficient to disclose whether scientists "significant either in number or expertise" accept as reliable, or oppose as unreliable, the new technology in question. (Shirley, supra, 31 Cal. 3d at p.56; see also Brown supra, 46 Cal. 3d at p.533).

Against this backdrop of guiding legal principles developed by Kelly and its progeny, this Court and counsel, after extensive discussions in chambers, framed the following statement of the issue to be presented at the Kelly hearing:

Is it the consensus of the relevant scientific community that a PET scan can reliably show injury to the brain as having been caused by blunt force trauma?

Dr. Joseph Wu also testified at a "Kelly" hearing in the California case to determine the admissibility of PET scan evidence. The Court accepted the evidence of Dr. Wu that the use of PET scans in detecting the location and extent of head injury is "well accepted" in the scientific community. The court also relied upon a report from Dr. Alavi who stated:

There is almost no question in the scientific community about its (PET's) value in demonstrating regional brain abnormalities within the capabilities of these techniques in many diseases of the brain that affect brain metabolism... *We now offer this methodology as a routine test to the clinicians who treat patients with head injuries.* [Emphasis added]

The defence relied on the evidence of Alan D. Waxman, Director of the Division of Nuclear Medicine at the Cedar-Sinai Medical Center in Los Angeles. Dr. Waxman testified that PET scanning was useful in showing head injuries in the moderate to severe range, but was not generally accepted by the relevant scientific community in showing minor head injuries. The Court rejected the evidence of the defence expert. The Judge stated:

In support of this opinion, Dr. Waxman relies heavily on a scientific paper submitted by the defendants entitled 'Ethical Clinical Practices of Functional Brain Imaging,' prepared by the Brain Imaging Council of the Society of Nuclear Medicine and appearing in the July, 1996, issue of the Journal of Nuclear Medicine. His reliance on the paper is misplaced, for two reasons:

First, the only reference which this Court has been able to find in that paper to "mild" head injuries, as distinguished from moderate or major injuries is the following. 'In many cases, the patterns (of behavioral syndromes) are variable and not easily interpreted as being causally related to a particular disease entity (e.g.

mild head injury...)' That statement is not relevant to the issue at hand. We are only concerned with the narrow issue whether brain injury can reliably be shown by a PET scan, not whether a behavior pattern or any other mental or physical abnormality or characteristic can be causally related to brain injury.

Second, the authors of the paper write that in the forensic setting, the use of functional neuroimaging for various purposes, including personal injury, remains 'especially controversial.' The paper speaks to 'unsupportable conclusions' if PET observations are introduced as proof of the commission of a crime or the cause of an illness or injury. Again, Dr. Waxman draws on the paper as the basis for an opinion relating to causality, but the wrong causality. *The PET scans of the plaintiff are not being offered in this case as proof of the cause of illness or injury, or, in other words, to prove liability; they are being offered as proof that an abnormality exists in the plaintiff's brain which, to a reasonable medical certainty, was caused by blunt force trauma.* The cause of the blunt force trauma is an entirely different matter; it could have been one of an infinite number of causes. It will be the plaintiff's burden to prove, by the preponderance of the evidence, that the cause of the blunt force trauma was the automobile collision.

Apart from the paper on Ethical Clinical Practices discussed above, Dr. Waxman takes issue with Dr. Wu on the technical statistical issues involved in detecting minor head injuries with a PET scan. While finding no disagreement with Dr. Wu on the reliability of PET scans to show major or moderate head injuries (which neither witness defined) he nevertheless finds fault with Dr. Wu's claim to have detected minor head injuries because: Dr. Wu's data base is flawed; his results are not validated by tests - retests; his error rate is not shown; his double-blind tests for validation are non-existent, etc. We did not hear from Dr. Wu on these points of criticism at the hearing; and, in any event, this court finds nothing in the literature to suggest that the absence of these statistical refinements would undermine the reliability of Dr. Wu's presentation for the singular purpose of which it is being offered - functional brain abnormalities consistent with trauma.

The court concludes as follows:

1. The use of the PET scan to reliably show injury to the brain caused by blunt force trauma is generally accepted in the relevant scientific community; The evidence of such reliability has been furnished by a properly qualified expert (Dr. Wu); Proper scientific procedures were followed to produce the results being proffered; Dr. Wu's PET scans of plaintiff taken on February 18, 1998, are admissible;
2. Question such as the extent of the injury (minor, moderate or major - to be defined) or the effect of the patient's drug regimen on the results of the scans, or the passage of time between the trauma and the PET scans and questions of

like nature are questions of fact which go to the weight of the proffered evidence and not to its admissibility. [Emphasis added]

I am aware of a number of MTBI cases in British Columbia with positive PET scans where counsel will be seeking to introduce this evidence. It is likely that the defence will continue to challenge its admissibility and another voir dire will be required. I assume that given agreement of the defence experts that the PET is an appropriate neurodiagnostic tool in cases of moderate to severe TBI, the admissibility of the PET scan will not be challenged in these cases, although I expect they may challenge the interpretation. I had two cases of severe TBI where the initial CT scan showed evidence of damage to frontal and temporal areas of the brain. An MRI four years later showed damage in the same areas. A subsequent PET scan showed a lack of metabolic activity or alteration in brain function in the same areas as the CT and MRI scans. This seems to be very powerful evidence of reliability.

Craig Dennis has written an excellent paper, which is appended to this article that deals with the issue of the admissibility of novel scientific evidence. He considers the American cases and the recent decisions in Canada and offers some insightful comments on the decision in *Wolfenbarger* at page 11 of his paper:

The approach advocated by Dillon J. is of undoubted utility to an assessment of the overall value of the proffered scientific evidence. But, as the application of the standard in *Wolfenbarger* illustrates, it has a tendency to draw a court into a consideration of the substance of the scientific opinion. In support of the evidence's exclusion, Dillon J. considered both what the expert proposed to say and what he did not say. By so doing the Court may well have removed itself from a consideration of the strength of the "scientific process" and delved into an area that might better be left as a matter of weight for the trier of fact. Thus uncertainty as the test of reliability may well set the bar too high. The degree of scientific uncertainty is a consideration well suited for the trier of fact to take into account in deciding the weight to be accorded the expert opinion, but it is not clear why it should be the determinant of admissibility.

I am hopeful that the comments of Craig Dennis together with the experience gained from the *Wolfenbarger* decision will assist counsel to develop both the evidence and the arguments necessary to satisfy the appropriate test for admissibility of PET scans in future MTBI cases.